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| 10/761,940 | 01/21/2004 | Gyorgy Domany | 1000546-0003 | 4047 |

7590 12/26/2006
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| EXAMINER |
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CHANG, CELIA C

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| ART UNIT | PAPER NUMBER |
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1625

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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| 3 MONTHS | 12/26/2006 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

DETAILED ACTION

1. Applicant's election without traverse of group I, claim 15, with the species 2-[4-(4-fluoro-benzyl)-piperidin-1-yl]-2-oxo-N-(2-oxo-2,3-dihydro-benzoxazol-6-yl)-acetamide in the reply filed on Sept. 27, 2006 is acknowledged.

Based on the election, claim 15 and claims 1-4, 6-8, 10-11, 13-14, 16-37 reading on claim 15, wherein U-V forms a ring are prosecuted. Claims 5, 9, 12, 38 and the remaining subject matter of claims 1-4, 16-37 are withdrawn from consideration per 37 CFR 1.142(b).

Based on the election of claim 15, the subject matter wherein U-V forms a ring is examined while the subject matter being drawn to U and V are independent substituents will be restricted for the following reason. It has been documented that the core containing piperidine with U and V being independent substituents do not share the same utility as those wherein U-V are ring as the elected compounds. It is evidenced that the U and V are independent substituents compounds are neuropeptide Y5 ligands (see CA 142:240321).

The restriction is proper especially, it has been clearly found by the PCT search result that very large number of documents relevant to the issue of novelty were found initially, thus, only limited meaningful search was conducted.

2. Claims 1-4, 6-7, 10, 13, 16-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds wherein U-V forms ring as disclosed on page 5, lines 7-10, does not reasonably provide enablement for the unlimited scope of all heterocyclic rings encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

This is a scope of enablement rejection. Without description and specific provision of the starting material for such structure, the specification provided insufficient description as well as starting material sources for the breadth of the scope. Starting material at the point of novelty is particularly pertinent in chemical compounds since absent of starting material sources, the public is offered mere language rather than enablement. Ex parte Moersch 104 USPQ 122. In re Howarth 210 USPQ 289.

Art Unit: 1625

3. Claims 1-4, 6-8, 10-11, 13-14, 16-28 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916), where the Supreme Court looked to whether the experimentation needed to practice an invention was undue or unreasonable. *Id.* An invention must be described so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). As stated in the MPEP 2164.01(a) "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". The analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. *Id.* at 740, *Id.* at 1407. The factors to be considered herein are those set forth as the *In re Wands*, 8 USPQ 2nd 1400 (1988) decision.

The analysis is applied to the instant case.

Nature of invention

The claims are drawn to compounds and their composition for the use of treating pathologies requires antagonism of NMDA receptor.

The state of the art and predictability

Receptor binding requires very specific structural conformation of a given compound (see Silverman p.72-76). Especially in NMDA receptor binding field, it is well recognized in the art that potent NMDA receptor antagonists of similar chemical structure have severe side effects, thus, makes such compounds unable to be useful as drugs (see CA 145:158900).

Further, there are many subtypes of NMDA receptors and each subtype has independent and distinct physiological function for which a single compound does not operate multiple sites (see CA 141:47098).

The amount of guidance and working examples

The specification disclosed on pages 14-19 that examples of the prepared compounds have compatible activity as the known NMDA antagonists Ro 25-6981. Thus, the compounds

Art Unit: 1625

have limited nexus based on the compatibility with Ro 25-6981 for operability of the conventionally known pathology for Ro 25-6981 i.e. ischemic damage of the brain (see CA 142:232125, Richter) for compounds of claim 15. The specification together with the complexity of the field provided no description or enablement for the compounds to be operable for *all* NMDA receptor antagonistic activity including those have not yet been discovered at the time the invention was made.

4. Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

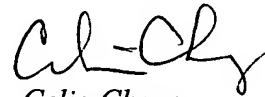
The closest prior art (UD 6,399,631, col. 69, compound 69) differ from the instant claim 15 in that the U-V fused ring system was further fused with an additional benzene and X is an isostere instead of carbonyl. Therefore, compounds of claim 15 limited to the particularly disclosed bicyclic ring system of claim 14 are neither anticipated nor rendered obvious by the art of record.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Dec. 20, 2006


Celia Chang
Primary Examiner
Art Unit 1625